



**MRID
NUMBER**

462563-00

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter:

MILES INC.
 AGRICULTURE DIVISION
 P.O. Box 4-13
 Kansas City, Missouri 64120

John S. Thornton
 John S. Thornton, Manager
 Registrations
 Research and Development
 (816) 242-2255

2. Regulatory Action in Support of Which This Package is Submitted:

The studies listed in Section 4 of this document are submitted to support the registration of five new insecticide products containing a new active ingredient - NTN 33893. Specifically, the new products are NTN 33893 Technical, NTN 33893 75% Concentrate, NTN 33893 0.62% Granular, NTN 33893 2.5% Granular and NTN 33893 2. Regulatory actions on this active ingredient have been assigned to Mr. Dennis H. Edwards, Jr., Product Manager 19, Registration Division.

3. Transmittal Date:

March 16, 1992

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Study No.</u>	<u>PRODUCT CHEMISTRY</u>
-----------------	------------------	--------------------------

42256301

- | | |
|---|---|
| 1 | "Product Chemistry of BAY NTN 33893 2.5% Granular," EPA Guideline Nos. 61-1 to 61-2(b), 62-1 to 62-3, 63-1 to 63-21, and 64-1, Miles Brochure No. 1767, T.D. Talbott, 38 p. |
|---|---|

42256302

- | | |
|---|---|
| 2 | "Product Chemistry of BAY NTN 33893 240 FS," EPA Guideline Nos. 61-1 to 61-2(b), 62-1 to 62-3, 63-1 to 63-21 and 64-1, Miles Brochure No. 1766, T.D. Talbott, 43 p. |
|---|---|

WILDLIFE AND AQUATIC ORGANISMS DATA REQUIREMENTS

42256303

- | | |
|---|---|
| 3 | "Acute Toxicity of NTN 33893 to <u>Hyla</u> <u>azteca</u> ," EPA Guideline No. 72-2, Miles Report No. 101960, D. England and J. Bucksath, 29 p. |
|---|---|

17/3

- 42256304 4 "Growth and Survival of the Midge (Chironomus tentans)," There is no EPA Guideline No. for this study, Miles Report No. 101985, G.G. Gagliano, 43 p.
- 42256305 5 "NTN 33893 Technical: Acute Effect on New Shell Growth of The Eastern Oyster, Crassostrea virginica," EPA Guideline No. 72-3, Miles Report No. 101978, J. Wheat and G. Ward, 54 p.
- 42256306 6 "Assessment of the Potential Ecological and Biological Effects of NTN 33893 on Aquatic Ecosystems as Measured in Fiberglass Pond Systems," EPA Guideline No. 72-7, Miles Report No. 102600, J. Moring, J. Kennedy and J. Wiggins, 791 p.
- 42256307 7 "Evaluation of the Foliar Half-life and Distribution of NTN 33893 in Turf," There is no EPA Guideline No. for this study, Miles Report No. 102605, J. Lin, 164 p.
- 42256308 8 "NTN 33893: Turf Runoff Predictions and Microcosm Loading Rates," There is no EPA Guideline No. for this study, Miles Report No. 102601, J. Lin and R. Graney, 85 p.
- 42256309 9 "Field Measurement of NTN 33893 (Imidacloprid) Runoff From Small Turf Plots in Miles Research Park, Stilwell, Kansas," There is no EPA Guideline No. for this study, Miles Report No. 102606, J. Lin, 135 p.
- 42256310 10 "Ecological Effects Summary and Risk Assessment for NTN 33893 Turf Insecticide: 240 FS Formulation," There is no EPA Guideline No. for this study, Miles Report No. 102602, R. Graney and D. Fischer, 63 p.
- 42256311 11 "An Overview of the Toxicology of NTN 33893 and its Metabolite WAK 3839," There is no EPA Guideline No. for this study, Miles Report No. 102657, G.K. Sangha and L. Machemer, 134 p.
- 42256312 12 "Acute Oral Toxicity Study with BAY NTN-33893 75 WP-WS in Rats," EPA Guideline No. 81-1, Miles Report No. 101283, L. Sheets and S. Phillips, 20 p.

TOXICOLOGY DATA REQUIREMENTS

- 42256313 13 "Acute Oral Toxicity Study with BAY NTN 33893
240 F.S. in Rats," EPA Guideline No. 81-1, Miles
Report No. 100010, L. Sheets, 19 p.
- 42256314 14 "Acute Dermal Toxicity Study with BAY NTN 33893
75 WP-WS in Rats," EPA Guideline No. 81-2, Miles
Report No. 101281, L. Sheets and R. Gilmore, 19
p.
- 42256315 15 "Acute Dermal Toxicity Study with BAY NTN 33893
240 F.S. in Rabbits," EPA Guideline No. 81-2,
Miles Report No. 100002, L. Sheets, 18 p.
- 42256316 16 "Acute Four-Hour Inhalation Toxicity Study with
BAY NTN 33893 75% WP-WS in Rats," EPA Guideline
No. 81-3, Miles Report No. 101913, D. Warren, 34
p.
- 42256317 17 "Acute Four-Hour Inhalation Toxicity Study with
BAY NTN 33898 240 F.S. in Rats," EPA Guideline
No. 81-3, Miles Report No. 100012, D. Warren, 28
p.
- 42256318 18 "Primary Eye Irritation Study with BAY NTN 33893
75 WP-WS in Rabbits," EPA Guideline No. 81-4,
Miles Report No. 101259, L. Sheets and S.
Phillips, 17 p.
- 42256319 19 "Primary Eye Irritation Study with BAY NTN 33893
240 F.S. in Rabbits," EPA Guideline No. 81-4,
Miles Report No. 99815, L. Sheets, 17 p.
- 42256320 20 "Primary Dermal Irritation Study with BAY NTN
33893 75 WP-WS in Rabbits," EPA Guideline No.
81-5, Miles Report No. 101278, L. Sheets and S.
Phillips, 17 p.
- 42256321 21 "Primary Dermal Irritation Study with BAY NTN
33893 240 F.S. in Rabbits," EPA Guideline No.
81-5, Miles Report No. 99816, L. Sheets; 16 p.
- 42256322 22 "Dermal Sensitization Study with BAY NTN 33893
75 WP-WS in Guinea Pigs," EPA Guideline No. : :
81-6, Miles Report No. 101282, L. Sheets and S. : :
Phillips, 23 p. : :
- 42256323 23 "Dermal Sensitization Study with BAY NTN 33893 : :
240 F.S. in Guinea Pigs," EPA Guideline No. : :
81-6, Miles Report No. 100003, L. Sheets; 21 p. : :
: : :

42256324	24	"NTN 33893 Study for Acute Oral Toxicity to Mice," There is no EPA Guideline No. for this study, Miles Report No. 100039, W. Bommann, 48 p.
42256325	25	"NTN 33893 Acute Toxicity Study on Mice," There is no EPA Guideline No. for this study, Miles Report No. 100681, Y. Nakazato, 6 p.
42256326	26	"NTN 33893 (c.n. Imidacloprid [proposed] Study for Acute Intraperitoneal Toxicity in Rats," There is no EPA Guideline No. for this study, Miles Report No. 100689, F. Krotlinger, 67 p.
Rejected (27)	27	"NTN 33893 (Proposed Common Name: Imidacloprid) Subacute Inhalation Toxicity Study on the Rat According to OECD Guideline No. 412," There is no EPA Guideline No. for this study, Miles Report No. 100262, J. Pauluhn, 662 p.
42256327	28	"NTN 33893 Subchronic Toxicity Study on Wistar Rats (Administration in the Feed for 96 Days)," EPA Guideline No. 82-1, Miles Report No. 100036, R. Eiben, 489 p.
42256328	29	"NTN 33893 Technical Subchronic Toxicity Study on Dogs in Oral Administration (Thirteen-Week Study Feeding)," EPA Guideline No. 82-1, Miles Report No. 100176, J. Ruf, 305 p.
42256329	30	"NTN 33893 Techn. Study for Subacute Dermal Toxicity in the Rabbit," EPA Guideline No. 82-2, Miles Report No. 100688, W. Flucke, 140 p.
42256330	31	"28-Day Oral Range-Finding Toxicity (Feeding) Study with NTN 33893 Techn. in the Dog," There is no EPA Guideline No. for this study, Miles Report No. 99656, I. Bloch, 172 p.
42256331	32	"NTN 33893 (Proposed Common Name: Imidacloprid) Chronic Toxicity and Cancerogenicity Studies on Wistar Rats (Administration in Food Over 24 Months)," EPA Guideline No. 83-1, Miles Report No. 100652, R. Eiben and G. Kaliner, 1323 p.
42256332	33	"NTN 33893 (Proposed Common Name: Imidacloprid) Chronic Toxicity and Carcinogenicity Studies on Wistar Rats (Administration in Food Over 24 Months) Supplementary MTD Study for Two-Year Study T 1025699," EPA Guideline No. 83-1, Miles Report No. 101021, R. Eiben, 971 p.

- 42256333 34 "Expert Opinion on the Occurrence of Mineralized Particles in the Colloid of the Thyroid Glands in Aging Rats," There is no EPA Guideline No. for this study, Miles Report No. 102658, G. Kaliner, 7 p.
- 42256334 35 "NTN 33893 Pilot Range-Finding Study for a Chronic Toxicity Study on Wistar Rats (Ninety-Eight Day Feeding Study)," There is no EPA Guideline No. for this study, Miles Report No. 99672, R. Eiben, 147 p.
- REJECTED (36) 36 "52-Week Oral Toxicity (Feeding) Study with NTN 33893 Technical in the Dog," EPA Guideline No. 83-1, Miles Report No. 100015, T. Allen, Th. Frei, H. Luetkemeier, O. Voegel, K. Biedermann and J. Wilson, 454 p.
- 42256335 37 "NTN 33893 (proposed common name Imidacloprid) Carcinogenicity Study on B6C3F1 Mice (Administration in the Food for 24 Months), EPA Guideline No. 83-1, Miles Report No. 100693, B. Watta-Gebert, 1318 p.
- 42256336 38 "NTN 33893 (Proposed Common Name: Imidacloprid) Carcinogenicity Study in B6C3F1 Mice (Supplementary MTD Testing for Study T 5025710 With Administration in Diet Over a 24-Month Period)," EPA Guideline No. 83-1, Miles Report No. 101929, B. Watta-Gebert, 732 p.
- 42256337 39 "NTN 33893 Pilot Range-Finding Study for a Cancerogenesis Study on B6C3F1 Mice (One Hundred Seven Day Feeding Study)," There is no EPA Guideline No. for this study, Miles Report No. 99608, R. Eiben, 119 p.
- 42256338 40 "Embryotoxicity Study (Including Teratogenicity) With NTN 33893 Technical in the Rat," EPA Guideline No. 83-3, Miles Report No. 98571, H. Becker, W. Vogel and Ch. Terrier, 288 p.
- 42256339 41 "Embryotoxicity Study (Including Teratogenicity) With NTN 33893 Technical in the Rabbit," EPA Guideline No. 83-3, Miles Report No. 98572, H. Becker and K. Biedermann, 237 p.
- 42256340 42 "NTN 33893 Technical (Proposed C.N. Imidacloprid) Multiple Generation Reproduction Study in Rats," EPA Guideline No. 83-4, Miles Report No. 100647, P. Suter, K. Biedermann, H. Luetkemeier, J. Wilson and Ch. Terrier, 1729 p.

5

42256341

- 43 "NTN 33893 Reverse Mutation Assay (Salmonella typhimurium and Escherichia coli)," EPA Guideline No. 84-2, Miles Report No. 101276, M. Watanabe, 28 p.

42256342

- 44 "NTN 33893 Mutagenicity Study for the Detection of Induced Forward Mutations in the CHO-HGPRT Assay in Vitro," EPA Guideline No. 84-2, Miles Report No. 98584, H. Lehn, 33 p.

42256343

- 45 "NTN 33893 Salmonella/Microsome Test to Evaluate for Point Mutagenic Effects," EPA Guideline No. 84-2, Miles Report No. 98570, B. Herbold, 45 p.

42256344

- 46 "NTN 33893 In Vivo Cytogenetic Study of the Bone Marrow In Chinese Hamster to Evaluate for Induced Clastogenic Effects," EPA Guideline No. 84-2, Miles Report No. 100021, B. Herbold, 36 p.

42256345

- 47 "NTN 33893 In Vitro Cytogenetic Study with Human Lymphocytes for the Detection of Induced Clastogenic Effects," EPA Guideline No. 84-2, Miles Report No. 99262, B. Herbold, 36 p.

42256346

- 48 "NTN 33893 Sister Chromatid Exchange in Bone Marrow of Chinese Hamsters In Vivo," EPA Guideline No. 84-2, Miles Report No. 99257, B. Herbold, 36 p.

42256347

- 49 "NTN 33893 Micronucleus Test on the Mouse to Evaluate for Clastogenic Effects," EPA Guideline No. 84-2, Miles Report No. 102652, B. Herbold, 31 p.

42256348

- 50 "Mouse Germ-Cell Cytogenetic Assay with NTN 33893," EPA Guideline No. 84-2, Miles Report No. 102654, W. Volkner, 27 p.

42256349

- 51 "Clastogenic Evaluation of NTN 33893 in an In Vitro Cytogenetic Assay Measuring Sister Chromatid Exchange in Chinese Hamster Ovary (CHO) Cells," EPA Guideline No. 84-2, Miles Report No. 102655, R. Taalman, 24 p.

•••••
•••••
•••••
•••••

6

- 42256350 52 "Sister Chromatid Exchange Assay in Chinese Hamster Ovary Cells," EPA Guideline Nos. 84-3 and 84-4, Miles Report No. 99676, D. Putman, M. Morris, 26 p.
- 42256351 53 "NTN 33893 Rec-assay with Spores in the Bacterial System," EPA Guideline No. 84-4, Miles Report No. 101275, M. Watanabe, 25 p.
- 42256352 54 "Mutagenicity Test on NTN 33893 In the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay," EPA Guideline No. 84-4, Miles Report No. 98573, M. Cifone, 29 p.
- 42256353 55 "NTN 33893 Test on S. Cerevisiae D7 to Evaluate for Induction of Mitotic Recombination," EPA Guideline No. 84-4, Miles Report No. 102653, B. Herbold, 28 p.
- 42256354 56 "Methylene-[¹⁴C] Imidacloprid: Metabolism Part of the General Metabolism Study in the Rat," EPA Guideline No. 85-1, Miles Report No. 101999, O. Klein and W. Karl, 101 p. plus page 78A and 78B for a total of 103 p.
- 42256355 57 "[¹⁴C]-NTN 33893: Investigations on the Distribution of the Total Radioactivity in the Rat by Whole-Body Autoradiography," There is no EPA Guideline No. for this study, Miles Report No. 87264, O. Klein, 28 p.
- 42256356 58 "[¹⁴C]-NTN 33893: Biokinetic Part of the General Metabolism Study in the Rat," EPA Guideline No. 85-1, Miles Report No. 87265, O. Klein, 97 p.
- 42256357 59 "[Imidazolidine-4,5-¹⁴C] Imidacloprid: Investigation of the Biokinetic Behaviour and Metabolism in the Rat," EPA Guideline No. 85-1, Miles Report No. 102617, O. Klein and A. Brauner, 86 p.
- 42256358 60 "A Liquid Chromatographic Method for the Determination of NTN 33893 in Inhalation Chamber Atmospheres," There is no EPA Guideline No. for this study, Miles Report No. 99874, K. Moore, 14 p.

- 42256359 61 "A Liquid Chromatographic Method for the Determination of NTN 33893 in Aqueous Dose Mixtures," There is no EPA Guideline No. for this study, Miles Report No. 99875, K. Moore, 14 p.
- 42256360 62 "NTN 37571 Oral Acute Toxicity Study on Rats," EPA Guideline No. 81-1, Miles Report No. 100683, Y. Nakazato, 6 p.
- 42256361 63 "WAK 3839 Acute Oral Toxicity Study in Rats (Preliminary Study)," EPA Guideline No. 81-1, Miles Report No. 100682, Y. Nakazato, 6 p.
- 42256362 64 "WAK 3839 Subchronic Toxicological Study on Rats (Twelve-Week Administration in Drinking Water)," EPA Guideline No. 82-1, Miles Report No. 101949, F. Krottinger, 359 p.
- 42256363 65 "WAK 3839 Reverse Mutation Assay (Salmonella typhimurium and Escherichia coli)," EPA Guideline No. 84-2, Miles Report No. 100668, M. Watanabe, 26 p.
- 42256364 66 "WAK 3839 Mutagenicity Study for the Detection of Induced Forward Mutations in the V79-HGPRT Assay In Vitro," EPA Guideline No. 84-2, Miles Report No. 100662, H. Lehn, 32 p.
- 42256365 67 "WAK 3839 Mutagenicity Study for the Detection of Induced Forward Mutations in the CHO-HGPRT Assay In Vitro," EPA Guideline No. 84-2, Miles Report No. 100661, H. Lehn, 32 p.
- 42256366 68 "WAK 3839 or NTN 37571 Micronucleus Test on the Mouse After Intraperitoneal Injection," EPA Guideline No. 84-2, Miles Report No. 100664, B. Herbold, 38 p.
- 42256367 69 "NTN 37571 Micronucleus Test on the Mice after I.P. Treatment," EPA Guideline No. 84-2, Miles Report No. 100679, M. Usami, 10 p.
- 42256368 "WAK 3839 Micronucleus Test on the Mouse After Oral Application," EPA Guideline No. 84-2, Miles Report No. 100663, B. Herbold, 39 p.

- 42256369 71 "NTN 37571 Micronucleus Test on the Mice After Oral Treatment Pilot Study," EPA Guideline No. 84-2, Miles Report No. 100680, M. Usami, 10 p.
- 42256370 72 "Chromosome Aberration Assay in Chinese Hamster V79 Cells In Vitro with WAK 3839," EPA Guideline No. 84-2, Miles Report No. 100666, A. Heidemann, 45 p.
- 42256371 73 "NTN 37571 In Vitro Cytogenetic Assay Measuring Chromosome Aberrations in CHO-K1 Cells," EPA Guideline No. 84-2, Miles Report No. 100678, M. Usami, 13 p.
- 42256372 74 "Unscheduled DNA Synthesis in Primary Hepatocytes of Male Rats In Vitro with WAK 3839," EPA Guideline No. 84-4, Miles Report No. 100665, P. Fautz, 31 p.
- 42256373 75 "Imidacloprid - WAK 3839: Comparison of Biokinetic Behaviour and Metabolism in the Rat Following Single Oral Dosage and Investigation of the Metabolism After Chronic Feeding of Imidacloprid to Rats and Mice," EPA Guideline No. 85-1, Miles Report No. 100645, O. Klein, 85 p.

PLANT PROTECTION DATA REQUIREMENTS

- 42256374 76 "Growth Inhibition of Green Algae (Scenedesmus suspicatus) Caused by NTN 33893 (Technical)," EPA Guideline No. 122-2, Miles Report No. 100098, F. Heimbach, 17 p.
- 42256375 77 "Acute Toxicity of NTN 33893 Technical to the Green Alga (Selenastrum capricornutum)," EPA Guideline No. 123-2, Miles Report No. 101986, 30 p.

NONTARGET INSECT DATA REQUIREMENTS

- REJECTED (78) 78 "The Acute Oral and Contact Toxicity to Honey Bees of Compound NTN 33893 Technical," EPA Guideline No. 141-1, Miles Report No. 101321, J. Cole, 13 p.

ENVIRONMENTAL FATE DATA REQUIREMENTS

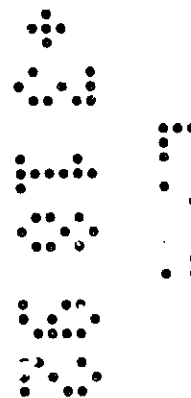
- 42256376 79 "Photodegradation of NTN 33893 in Water," EPA Guideline No. 161-2, Miles Report No. 101956, C. Anderson, 123 p.
- 42256377 80 "Photodegradation of NTN 33893 on Soil," EPA Guideline No. 161-3, Miles Report No. 100249, H. Yoshida, 42 p.
- 42256378 81 "Degradation of Pesticides Under Anaerobic Conditions in the System Water/Sediment: Imidacloprid, NTN 33893," EPA Guideline No. 162-3, Miles Report No. 101346, R. Fritz, and E. Hellpointner, 69 p.
- 42256379 82 "Terrestrial Field Dissipation for NTN 33893 in Georgia Soil," EPA Guideline No. 164-1, Miles Report No. 101987, F. Rice, D. Judy, D. Koch and K. Cain, 422 p.
- 42256380 83 "Terrestrial Field Dissipation for NTN 33893 in Minnesota Soil," EPA Guideline No. 164-1, Miles Report No. 101988, F. Rice, D. Judy, D. Koch, and K. Cain, 510 p.
- 42256381 84 "Terrestrial Field Dissipation for NTN 33893 in California Soil," EPA Guideline No. 164-1, Miles Report No. 101989, F. Rice, D. Judy, D. Koch, and K. Cain, 561 p.
- 42256382 85 "Terrestrial Field Dissipation in Turf for NTN 33893 in Georgia," EPA Guideline No. 164-1, Miles Report No. 102603, F. Rice, D. Schwab, P. Noland and K. Cain, 353 p.
- 42256383 86 "Terrestrial Field Dissipation in Turf for NTN 33893 in Minnesota," EPA Guideline No. 164-1, Miles Report No. 102604, F. Rice, D. Schwab, P. Noland and K. Cain, 409 p.
- 42256384 87 "Analytical Method for the Determination of NTN 33893 in Soil Samples," EPA Guideline No. 164-1, Miles Report No. 101984, P. Noland and D. Koch, 82 p.

42256385

88 "Analytical Method for the Determination of NTN 33893 in Turf Samples," EPA Guideline No. 164-1, Miles Report No. 101981, P. Noland and D. Koch, 64 p.

42256386

89 "Mixer/Loader and Applicator Exposure Estimates for NTN 33893 Insecticide," EPA Guideline Nos. 231 and 232, Miles Report No. 94273, D. Eberhart, 12 p.



11



Agriculture Division

March 16, 1992

Miles Inc.
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

Mr. Dennis H. Edwards, Jr.
Product Manager (19)
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Subject: Registration Applications for Products Containing the New Active
Ingredient NTN 33893

Dear Mr. Edwards:

As you are aware, Miles is developing a new chemical for use as an insecticide. This new active ingredient - NTN 33893, proposed common name is imidacloprid - has been the subject of a number of pre-registration conferences with you, Ms. Portia Jenkins of your staff and various other Agency personnel.

Miles has also applied for two Experimental Use Permits (EUP's) for a 0.62% granular formulation of this active ingredient. The Agency File Symbol Nos. for these EUP's are 3125-EUP-ENR and 3125-EUP-ENG.

Enclosed are applications for the first full registrations of products containing this new active ingredient, NTN 33893.

There are two registration applications for manufacturing use products - NTN 33893 Technical and NTN 33893 75% Concentrate.

There are three applications for end use products. Two of the products, NTN 33893 0.62% Granular and NTN 33893 2.5% Granular, are for use only on ornamentals. The third end use product, NTN 33893 2, is for use on ornamentals, lawns and turfgrasses.

Although Miles is developing NTN 33893 products for various food uses, the enclosed applications are only for non-food uses. Later this calendar year Miles will be submitting for the first food uses and tolerances for NTN 33893.

To support the registration of these five products, we are enclosing three copies of 89 Miles reports/brochures along with the three copies of the appropriate transmittal document for these reports/brochures.

12


Enclosed with this letter is a document detailing the list of data requirements pursuant to 40 CFR 158 for these proposed registrations of products containing NTN 33893 and how each requirement is being addressed. All the required data are enclosed or have already been submitted to the Agency (40 Miles reports/brochures) under EPA File Symbol No. 3125-EUP-ENR. Those data previously submitted are cited in this document also by EPA MRID No.

Please note, the product NTN 33893 75% Concentrate is sometimes cited in the enclosed reports as NTN 33893 75 WP-WS. Also, the product NTN 33893 2 is sometimes cited in the enclosed reports as NTN 33893 240 FS.

If you have any questions regarding this submission, please contact Terry McNamara of my staff as soon as possible at 816/242-2327.

Yours very truly,

MILES INC.
AGRICULTURE DIVISION


John S. Thornton
Manager
Registrations

JST:FTM:brh

cc: Ms. Portia Jenkins
Product Team 19 H7505C

13

END